

### **REMARKS**

Claims 1-5 are pending. Claims 6-10 have been withdrawn. Applicant respectfully traverses the rejections in the outstanding Office Action, and submits that Claims 1-5 contain patentable material in view of the following comments.

#### ***Claim Rejections – 35 USC §102***

Claim 1 is rejected under 35 USC 102(b) as being anticipated by Bell (U. S. 5,679,309). Regarding Claim 1, the Examiner cites Bell for disclosing a method to increase analyzer throughput "using reagents inventoried in at least two servers wherein a first pattern of assays is to be performed in a first time period and a different second pattern of assays is to be performed in a different second time period, the method comprising duplicating reagents required to conduct a number of assays in the first pattern of assays within the at least two servers." (underlining added for emphasis)

Applicant respectfully suggests that The Examiner's description of Bell's disclosure is erroneous because Bell discloses only one reagent server.

The Examiner suggests that Bell discloses the combination of **30**, **16** and **20** as one reagent server and **46**, **28** and **26** as another. However, Bell's elements **30**, **16** and **20** are a sample transfer station **30**, a sample sector **16** and a sample wheel **20**. It is well understood that samples are biological fluids such as urine, blood serum, plasma, cerebrospinal fluid and the like. These samples are contained in sample vials, placed on an analyzer, combined with various chemical reagents and the resulting mixture is analyzed to aid in treatment of a patient. Thus, Bell's sample transfer station **30**, sample sector **16** and a sample wheel **20** are only sample handling elements and do not comprise a second reagent server.

Support for applicant's conclusion that Bell's analyzer has only a single reagent server can be found as follows:

1. Col. 5, lines 27-33 define **sample sector 16** as holding patient samples.
2. Col. 5, lines 38-48 define **sample wheel 20** as holding individual samples.
3. Col. 6, lines 35-42 define **sample transfer station 30** as transferring sample from sample wheel 20 to a test cuvette 24.
4. Col. 6, lines 30-31 distinguish between **sample wheel 20** and **reagent wheel 26**

MPEP 706.02 V requires that for an anticipation rejection under 35 U.S.C. 102(b) to be valid, the reference must teach every aspect of the claimed invention either explicitly or impliedly. Any feature not directly taught must be inherently present. Because Bell discloses only one single reagent server **46, 28 and 26**, it cannot be said that Bell anticipates Applicant's method for increasing the throughput of a clinical analyzer by duplicating reagents within at least two reagent servers as is required by Claim 1.

Furthermore, Bell does not inherently require that the features of Claim 1 be present to practice his invention since only the single reactant carousel **26** is needed. Applicant points out that if Bell's sample wheel **20** were a reagent wheel, as suggested by the Examiner, Bell's analyzer would be non-functional since there would be no provision within the analyzer for samples to be available for analysis.

Applicant therefore submits that the outstanding rejection under 35 USC 102(b) as being anticipated by Bell is improper and respectfully requests that the rejection of Claim 1 under 35 USC 102(b) be withdrawn.

***Claim Rejections – 35 USC §102(e)***

Claims 1, 2 and 5 are rejected under 35 USC 102(e) as being anticipated by Devlin (US 7,101,715). This rejection is traversed on the basis that Devlin does not disclose operating a single clinical analyzer having two servers, wherein reagents required to conduct assays in a first subgroup of assays (of the totality of assays to be conducted) are duplicated within the two servers as is claimed by applicant.

As explained below, the Examiner has suggested that Devlin discloses a method for increasing throughput of a clinical analyzer adapted to perform a number of different assays using reagents inventoried in at least two servers.

Applicant respectfully suggests that Devlin discloses a method for operating an analytical analyzer system comprising a **pair of analyzers 10 and 11**, linked together by a sample rack shuttle **68**, in order to optimize throughput of the overall dual-analyzer system, regardless of the mix of assays to be performed (Col. 8, lines 34-37 and line 45). Devlin differentiates assays based on assay type and operates the dual-analyzer system **analyzers 10 and 11** such that the first analyzer **10** is equipped to perform a certain group of assays and that the second analyzer **11** is equipped to perform a different group of assays.

Regarding claim 1, applicant divides the totality of assays to be performed on a **single analyzer** into two patterns based on the time required to conduct an assay and then duplicates reagents required to conduct assays in one pattern within the two servers. In contrast, Devlin operates a dual analyzer system in which the assays conducted on the **two analyzers 10 and 11** are different groups of assays. Thus it cannot be said that Devlin anticipates Claim 1 because Devlin does not teach duplicating reagents required to conduct certain assays within the two servers of a single analyzer as is claimed by applicant.

Applicant therefore submits that the outstanding rejection under 35 USC 102(e) as being anticipated by Devlin is unjustified and respectfully requests that the rejection of Claim 1 be withdrawn.

With regard to the rejection of claims 2 and 5 under 35 USC 102(e), since independent claim 1 patentably distinguishes over Devlin and is allowable, claims 2 and 5 are at least allowable therewith because they depend from an allowable base claim. Consequently, the Examiner is requested to withdraw the rejections of claims 2 and 5 under 35 USC 102(e).

Claims 3 and 4 are rejected under 35 USC 102(e) as being anticipated by or, in the alternative, under 35 USC 103(a) as being obvious over Devlin (US 7,101,715).

With regard to the rejection of claims 3 and 4 under 35 USC 102(e), since independent claim 1 patentably distinguishes over Devlin and is allowable, claims 3 and 4 are at least allowable therewith because they depend from an allowable base claim. Consequently, the Examiner is requested to withdraw the rejections of claims 3 and 4 under 35 USC 102(e).

With regard to the rejection of claim 3 under 35 USC 103(a), the Examiner suggests that it is inherent in the Devlin "that the first or second group of assays would be completed in less than half or more than half of the operational cycle time because this would be dependent on the types or reactions and reagents used." This suggestion is traversed as explained below for at least two reasons.

Firstly, applicant suggests that there is no inherent relationship between the frequency at which an assay is requested to be performed and the time required to perform the assay. In clinical analysis, the time required to perform an assay depends on the analytical technique used to measure an analyte and different analytical techniques require different reagents, mixing times, incubation times, analysis times and the like. In other words, the analytical technique employed to measure an analyte, in combination with the physical design of an analyzer, determines the amount of time to conduct an assay and this is unrelated to the frequency at which an assay is performed. For example, as Devlin discloses at Col. 10, lines 23-25, "the frequency of assays requested by a number of different physicians varies both regionally and demographically". Applicant therefore suggests that the frequency an assay is requested is unrelated to the time required to conduct an assay as suggested by the Examiner.

Secondly, claim 3 further limits claim 2 which requires that the first pattern of assays (in Devlin the corresponding group would presumably be **A** and **B**) have a larger portion of a first group of assays and a smaller portion of a second group of assays and wherein the second pattern of assays (in Devlin the corresponding group would presumably be **A** and **C**) has a larger portion of said second group of assays and a smaller portion of said first group of assays. However, Devlin's first and second patterns (**A** and **B**) and (**A** and **C**) comprise an equal first group of assays (group **A**). In the alternative, if **B** was chosen as the larger first portion of assays, making **A** the smaller second portion of assays, then Devlin does not have both larger portion **A** and smaller second portions **A**, since portion **A** is the same. Devlin thus teaches away from claim 2 and cannot be said to make claim 3 depending therefrom obvious.

For these two reasons, applicant submits that the Examiner has failed to provide a convincing line of reasoning as to why the claimed invention would be obvious. Failing this, a *prima facie* case of obviousness over Devlin has not been established, and it is respectfully requested that the rejection of claim 3 under 35 USC 103(a) as being obvious over Devlin be withdrawn.

With regard to the rejection of claim 4 under 35 USC 103(a), since dependent claim 3 patentably distinguishes over Devlin and is allowable, claim 4 is at least allowable therewith because it depends from an allowable claim. Consequently, the Examiner is requested to withdraw the rejection of claim 4 under 35 USC 103(a).

### ***Claim Rejections –35 USC §103***

Claims 2-4 are rejected under 35 USC 103(a) as being unpatentable over Bell as applied to claim 1. This rejection is traversed on the basis that Bell does not disclose a single clinical analyzer having two servers.

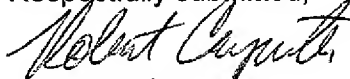
Regarding claim 2, the Examiner suggests that "Bell is capable of performing multiple assays using the **multiple** (reagent) servers found in Bell." As explained above, Bell's elements **30**, **16** and **20** are only a sample transfer station **30**, a sample sector **16** and a sample wheel **20** and cannot comprise a second reagent server as suggested. Claim 2 requires increasing the throughput of a clinical analyzer by duplicating reagents required to conduct assays in a first pattern of assays within at least two reagent servers. Since Bell has only a single reagent server, a *prima facie* case of obviousness not been established, and it is respectfully requested that the rejection of claim 2 under 35 USC 103(a) as being obvious over Bell be withdrawn.

With regard to the rejection of claims 3 and 4 under 35 USC 103(a), since claim 2 patentably distinguishes over Bell and is allowable, claims 3 and 4 are at least allowable therewith because they depend from an allowable claim. Consequently, the Examiner is requested to withdraw the rejection of claims 3 and 4 under 35 USC 103(a).

### **Conclusion**

Applicant believes that this application contains patentable subject matter and that the foregoing explanation provides a basis for favorable consideration and allowance of all claims; such allowance is respectfully requested. If any matter needs to be resolved before allowance, the Examiner is encouraged to call Applicant's representative at the number provided below.

Respectfully submitted,

  
Robert N. Carpenter  
Registration No. 40,409  
Attorney for Applicant

Siemens Healthcare Diagnostics (formerly Dade Behring Inc.)  
1717 Deerfield Road  
P. O. Box 778  
Deerfield, IL 60015-778  
(847) 267-5365